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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,696

12/03/2003

Chaitan Khosla

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25225 7590 07/09/2008  
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EXAMINER

KIM, ALEXANDER D

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,696	<b>Applicant(s)</b> KHOSLA ET AL.	
	<b>Examiner</b> ALEXANDER D. KIM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,10-13 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,10-13 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. The art unit location of your application and/or examiner has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1656, Examiner Alexander Kim.

2. In response to the previous Office action, a non-Final rejection (mailed on 10/26/2007), Applicants filed a response and amendment received on 02/26/2008. Said amendment cancelled Claims 6, 8-9 and 14-30; amended Claims 1 and 7.

Claims 1-5, 7, 10-13 and 31 are pending in the instant Office action and will be examined herein.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 12/11/2007 was filed after the mailing date of the non-final office action on 10/26/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objection***

4. Claim 7 is objected to because it recites "said a second nucleic acid" (see 5th line in Claim 7). It should be --- a second nucleic acid ---. Appropriate correction is required.

***Withdrawn-Claim Rejections - 35 USC § 112***

5. The previous rejection of Claims 1-5 and 31 under 35 U.S.C. 112, first paragraph, New Matter, because the term "essentially" expands the scope of the teaching of the original disclosure, is withdrawn by virtue of Applicants' amendment.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***New Matter***

6. Claims 1-5 and 31 are rejected under 35 U.S.C. 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is necessitated by the instant amendment of Claim 1 replacing "comprises" into "consists of".

As written, the instant claims are drawn to method for modifying a nucleotide sequence --- "consists of" (a) excising --- and (b) ligating ---, which is the method without any other additional method step(s) other than what is recited in Claim 1; wherein said instant claimed method is not supported by the original disclosure. The

applicant is advised to point out the support in the original disclosure or amend the instant claims.

***Withdrawn-Claim Rejections - 35 USC § 102***

7. The previous rejection of Claims 1-5 and 31 under 35 U.S.C. § 102(b) as being anticipated by Katz et al. (Katz, WO 93/13663) is withdrawn by virtue of Applicants' amendment which reciting method step "consists of" (a) excising and (b) ligating, whereas Katz et al. teach a method comprising (a) excising and (b) ligating as described in Claims 1-5 and 31 (differences emphasized with underline).

8. The previous rejection of Claims 1-5 and 31 under 35 U.S.C. § 102(e) as being anticipated by Katz et al. (US Patent 5,824,513, IDS reference number 5) is withdrawn by virtue of Applicants' amendment which reciting method step "consists of" (a) excising and (b) ligating, whereas Katz et al. teach a method comprising (a) excising and (b) ligating as described in Claims 1-5 and 31 (differences emphasized with underline).

***Withdrawn-Claim Rejections - 35 USC § 103***

9. The previous rejection of Claims 1-5 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Katz (WO 93/13663) or U. S. P 5,824,513 ('513, IDS reference number 5) or in view of the state of the art as exemplified by Kao *et al.* (IDS reference: Science 1994, 265, 509-512) is withdrawn for the same reason stated above in 35 USC §102 rejections.

***Maintained-Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7 and 10-13, ~~and 31~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over by Katz (WO 93/13663) or U. S. P 5,824,513 ('513, IDS reference number 5) in view of the state of the art as exemplified by Kao *et al.* (IDS reference: Science 1994, 265, 509-512).

The rejection was stated in the previous office action as it applied to previous Claims 1-5, 7, 10-13, and 31. In response to this rejection, applicants have cancelled Claims 6, 8-9 and 14-30; amended Claims 1 and 7; and traverse the rejection as it applies to the newly amended claims.

Applicants argue that Kao *et al.* "is irrelevant to these claims" (see page 7, line 12, Remarks filed on 2/28/2008) because there is no suggestion in Kao *et al.* "to exchange only portions of individual modules of modular PKS-encoding nucleotide sequences" (see page 7, lines 14-15, Remarks filed on 2/28/2008). Applicants further argue that Kao *et al.* do not teach a method of homologous recombinant techniques.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Kao *et al.* do not have to teach exchanging the individual modules of PKS-encoding nucleotide because the Katz *et al.* teach such

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method as recited in the previous office action (i.e., reciting "they teach that the extender unit employed at each condensation is specified by the acyltransferase function determined by each module, see page 6, lines 26-29", "a method for modifying the acyltransferase activity in a modular polyketide synthase by another acyltransferase activity, a modification described in the patent as type III changes, see column 4, lines 16-21", see bottom of page 4 in the previous Non-Final rejection mailed on 10/26/2007). However, the teaching of Kao et al. is "a method of constructing hybrid polyketide synthase for the production of novel polypeptides" "comprising the desired modified nucleic acid sequence attached to ~~flaking~~ flanking sequences at the 5'- and 3'- end that would allow homologues recombination" (see middle of page 5 in the previous Non-Final rejection mailed on 10/26/2007). For the reasons above and disclosure of the previous non-final office action, the instant rejection is maintained.

### ***Conclusion***

11. Claims 1-5, 7, 10-13 and 31 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/  
Examiner, Art Unit 1656

/Chih-Min Kam/  
Primary Examiner, Art Unit 1656